UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
BOWLING GREEN DIVISION

CIVIL ACTION NO. 1:15-CV-00057-JHM

SUSAN KAY WILLIS and WILLIE R. WILLIS, both individually and as parents and natural guardians of K.R.W. and K.W.W., minors — **PLAINTIFFS**

v.

ABBOTT LABORATORIES and ABBVIE, INC. — **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

This matter is before the Court on a motion for summary judgment by defendants Abbott Laboratories and Abbvie, Inc. (collectively "Abbott") (DN 95), as well as a motion for partial summary judgment by plaintiffs Susan and Willie Willis, individually and as parents and natural guardians of their children K.R.W. and K.W.W. (DN 80.) Also before the Court are three motions by Abbott to exclude the testimony of expert witnesses for the plaintiffs: Dr. Michael Cecil (DN 87), Dr. Robert J. Lerer (DN 89), and Dr. Michael Privitera. (DN 92.) Fully briefed, these matters are ripe for decision.

I. BACKGROUND

A. SUSAN WILLIS

Susan Willis was diagnosed with juvenile myoclonic epilepsy at the age of fifteen in 1995. (Dep. David Blake [DN 62-1] at 36:13–20.) She was prescribed Depakote, an antiepileptic drug ("AED"), to help control her condition. (*Id.* at 43:3–21.) Susan continued to take Depakote and was taking it when she became pregnant with K.R.W. around August 2001. (Dep. Susan Willis [DN 72-1] at 94:23–95:7.) However, she was switched from Depakote to

Dilantin, a different AED, at some point in September 2001 after discovering she was pregnant. (*Id.* at 95:9–96:10.) K.R.W. was born on April 22, 2002. (Lerer Report [DN 81-1] at 5.)

Susan remained on Dilantin until May 2003, when she began taking Depakote again. (Dep. Susan Willis [DN 72-1] at 124:3–11.) She became pregnant with K.W.W. around December 2005 and continued to take Depakote throughout her pregnancy. (*Id.* at 129:14–23; Lerer Report [DN 81-1] at 6.) K.W.W. was born on September 12, 2006. (*Id.*) K.R.W. and K.W.W. suffer from various physical deformities and cognitive disabilities, which the plaintiffs attribute to Susan's use of Depakote during her pregnancies. (Pl.'s Compl. [DN 1] ¶¶ 57, 62.)

B. DEPAKOTE

Depakote is an AED that is manufactured and sold by Abbott.[1] It was approved by the Food and Drug Administration ("FDA") in 1983 for the treatment of absence seizures. (Dep. James Lavery [DN 50-1] at 196:9–16.) During both of Susan's pregnancies, the label for Depakote contained identical warnings about the risk of birth defects. (*See* 2001 Physicians' Desk Reference [DN 95-3] at 5–6, 8; 2006 Physicians' Desk Reference [DN 95-4] at 3, 5–6.) Each label had a "black box warning" regarding the drug's teratogenic effects:

> **TERATOGENICITY:**
>
> VALPROATE[2] CAN PRODUCE TERATOGENIC EFFECTS SUCH AS NEURAL TUBE DEFECTS (E.G., SPINA BIFIDA). ACCORDINGLY, THE USE OF DEPAKOTE TABLETS IN WOMEN OF CHILDBEARING POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED AGAINST THE RISK OF INJURY TO THE FETUS. THIS IS ESPECIALLY IMPORTANT WHEN THE TREATMENT OF A SPONTANEOUSLY REVERSIBLE CONDITION NOT ORDINARILY ASSOCIATED WITH PERMANENT INJURY OR RISK OF DEATH (E.G., MIGRAINE) IS

[1] In 2013, Abbott Laboratories transferred ownership of the "New Drug Application" for Depakote to Abbvie. (Pl.'s Compl. [DN 1] ¶ 14.) For the purposes of this motion, there is no meaningful distinction between Abbott Laboratories and Abbvie, Inc.

[2] Valproate is the active ingredient in Depakote.

> CONTEMPLATED. SEE WARNINGS, INFORMATION FOR PATIENTS.
>
> AN INFORMATION SHEET DESCRIBING THE TERATOGENIC POTENTIAL OF VALPROATE IS AVAILABLE FOR PATIENTS.

(*Id.*) (emphasis in original). Following the black box warning, in the ordinary "Warnings" section, the label also states the following:

> **Usage in Pregnancy**
>
> ACCORDING TO PUBLISHED AND UNPUBLISHED REPORTS, VALPROIC ACID MAY PRODUCE TERATOGENIC EFFECTS IN THE OFFSPRING OF HUMAN FEMALES RECEIVING THE DRUG DURING PREGNANCY. THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS. THEREFORE, ANTIEPILEPSY DRUGS SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING POTENTIAL ONLY IF THEY ARE CLEARLY SHOWN TO BE ESSENTIAL IN THE MANAGEMENT OF THEIR SEIZURES.
>
> THE INCIDENCE OF NEURAL TUBE DEFECTS IN THE FETUS MAY BE INCREASED IN MOTHERS RECEIVING VALPROATE DURING THE FIRST TRIMESTER OF PREGNANCY. THE CENTERS FOR DISEASE CONTROL (CDC) HAS ESTIMATED THE RISK OF VALPROIC ACID EXPOSED WOMEN HAVING CHILDREN WITH SPINA BIFIDA TO BE APPROXIMATELY 1 TO 2%. OTHER CONGENITAL ANOMALIES (E.G., CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED. SUFFICIENT DATA TO DETERMINE THE INCIDENCE OF THESE CONGENITAL ANOMALIES IS NOT AVAILABLE. THE HIGHER INCIDENCE OF

> CONGENITAL ANOMALIES IN ANTIEPILEPTIC DRUG-TREATED WOMEN WITH SEIZURE DISORDERS CANNOT BE REGARDED AS A CAUSE AND EFFECT RELATIONSHIP. THERE ARE INTRINSIC METHODOLOGIC PROBLEMS IN OBTAINING ADEQUATE DATA ON DRUG TERATOGENICITY IN HUMANS; GENETIC FACTORS OR THE EPILEPTIC CONDITION ITSELF, MAY BE MORE IMPORTANT THAN DRUG THERAPY IN CONTRIBUTING TO CONGENITAL ANOMALIES.

(*Id*.) (emphasis in original).

During Susan's pregnancies, the Depakote label contained no warnings regarding the risk of cognitive developmental delay from in utero exposure to Depakote. However, in 2005 and 2007, Abbott sent correspondence to Dr. Russell Katz of the FDA suggesting revisions to the Depakote label. (*See* 2005 FDA Correspondence [DN 95-10]; 2007 FDA Correspondence [DN 95-12].) In both letters, Abbott noted that it had monitored and reviewed the available safety data on Depakote use during pregnancy and suggested the following update to the "WARNINGS – Usage in Pregnancy" section of the label: "There have been reports of developmental delay in the offspring of women who have received valproate[3] during pregnancy." (2007 FDA Correspondence [DN 95-12] at 4.) In both instances, the FDA indicated that the data relied upon was insufficient to justify a label change at that time and that "the proposed sentence should not be incorporated into labeling." (2006 FDA Correspondence [DN 95-11] at 3.) (*See also* 2008 FDA Contact Report [DN 95-13] at 3) ("Dr. Katz stated they can not approve this labeling change at this time.") Further, in 2009 Abbott sent another letter to the FDA seeking "advice on the acceptability of [recent] data for use to support an amendment to the current label regarding the risk of developmental delay and/or autism/autism spectrum disorder with intrauterine exposure to valproate." (2009 FDA Correspondence [DN 95-14] at 4.) The FDA told Abbott

[3] The 2005 proposed warning uses the term "valproic acid" as opposed to "valproate." (2005 FDA Correspondence [DN 95-10] at 7.)

later in 2009 that "they were not ready to 'sign off on the labeling language.'" (2009 FDA Contact Report [DN 95-16] at 4.) The FDA finally approved a label change for Depakote in October 2011 that included a warning "pertaining to valproate and neurodevelopmental delay." (2011 FDA Correspondence [DN 95-20] at 2.)

C. PROCEDURAL HISTORY

Susan and her husband, Willie Willis, brought the present action against Abbott both individually and on behalf of their children. (Pl.'s Compl. [DN 1].) They assert seven state-law claims against Abbott related to the manufacturing, labeling, and sale of Depakote: strict products liability – design defect (Count I); strict products liability – failure to warn (Count II); negligence (Count III); negligent misrepresentation and fraud (Count IV); breach of express warranty (Count V); breach of implied warranty of merchantability (Count VI); and breach of implied warranty of fitness (Count VII). (*Id*. ¶¶ 82–168.) Abbott has moved for summary judgment as to all claims against it. (DN 95.) The plaintiffs have also moved for partial summary judgment on Abbott's defense of preemption. (DN 80.)

Both parties have also submitted motions to exclude or limit the testimony of a variety of experts. (*See* DN 83–94, 163.) Based upon the grounds asserted in the parties' motions for summary judgment, the Court need only decide three of these motions to exclude in order to effectively decide the summary judgment motions: those in relation to Dr. Michael Cecil (DN 87), Dr. Robert J. Lerer (DN 89), and Dr. Michael Privitera. (DN 92.) Therefore, the Court will defer consideration of any other motion to exclude or limit testimony until after the motions for summary judgment have been decided. Further, the Court will only consider the arguments made to exclude opinions related to causation at this time, as only those arguments are relevant

to deciding the motions for summary judgment. Any other arguments to exclude or limit testimony will be considered in a separate order.

II. STANDARD OF REVIEW

Before the Court may grant a motion for summary judgment, it must find that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the initial burden of specifying the basis for its motion and identifying that portion of the record that demonstrates the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Once the moving party satisfies this burden, the non-moving party thereafter must produce specific facts demonstrating a genuine issue of fact for trial. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 252 (1986).

Although the Court must review the evidence in the light most favorable to the non-moving party, the non-moving party must do more than merely show that there is some "metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Instead, the Federal Rules of Civil Procedure require the non-moving party to present specific facts showing that a genuine factual issue exists by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence . . . of a genuine dispute[.]" Fed. R. Civ. P. 56(c)(1). "The mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-moving party]." *Anderson*, 477 U.S. at 252.

III. DISCUSSION

Abbott has moved for summary judgment as to all counts. The plaintiffs have conceded any claims for breach of warranty (DN 141, at 39 n. 10); therefore, only Counts I–IV remain. The Court will first address the motions for summary judgment as to Abbott's preemption defense. Next, it will consider Abbott's argument regarding the plaintiffs' strict products liability – design defect claim. It will then consider Abbott's argument as to whether there is any evidence of causation, which will require the Court to decide the motions to exclude the testimony of Drs. Cecil, Lerer, and Privitera. Finally, the Court will address the plaintiffs' claims for negligent misrepresentation and fraud.

A. PREEMPTION

Abbott argues that any claim that is based upon its failure to adequately warn of the risk of cognitive developmental delay from in utero exposure to Depakote is preempted by federal law. A drug "manufacturer bears responsibility for the content of its label at all times." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009). However, the FDA "has the authority to reject any labeling changes," creating the possibility that a drug manufacturer's ability to change its label to comply with state tort law may be impeded by the FDA's labeling requirements. *Rheinfrank v. Abbott Labs.*, 680 F. App'x 369, 385 (6th Cir. 2017). Thus, if a drug manufacturer can "show by 'clear evidence,' that the FDA would have rescinded any change in the label," then the manufacture has sufficiently "demonstrate[d] that it would in fact have been impossible to do under federal law what state law required," and the requirements of the FDA preempt those of state tort law. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 n. 8 (2011) (quoting *Wyeth*, 555 U.S. at 571).

In deciding whether Abbott has presented clear evidence that the FDA would have rejected any label changes to address the risk of cognitive developmental delay, the Court does not write on a blank slate. In *Rheinfrank*, the Sixth Circuit affirmed the conclusion, by Judge Dlott of the Southern District of Ohio, that all claims based upon the failure to warn of the risk of cognitive developmental delay from in utero exposure to Depakote were preempted. 680 F. App'x at 385. Further, the "clear evidence" in that case is identical to the evidence Abbott has submitted in this case to demonstrate that the FDA would not have approved a change to the Depakote label to include a warning about the risk of cognitive developmental delay. In *Rheinfrank*, the district court considered Abbott's 2005 correspondence with Dr. Katz of the FDA that sought to add a warning about developmental delay (DN 95-10) and the FDA's subsequent rejection of this language. (DN 95-11.) It also considered Abbott's 2007 correspondence with the FDA that once again sought to strengthen the Depakote label as it pertained to developmental delay (DN 95-12) and the FDA's response that it "can not approve this labeling change at this time." (DN 95-13.) Finally, the district court considered Abbott's 2009 request for guidance from the FDA as to what should be included in the Depakote label regarding developmental delay (DN 95-14, 95-15) and the FDA's response that it was not ready at this time to support any label changes. (DN 94-16.) Based upon this evidence, the district court concluded that "[p]reemption is warranted because there is clear evidence the FDA would not have approved a change to the Depakote label adding a developmental delay warning prior to" the plaintiff's injuries. *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 766 (S.D. Ohio 2015). The Sixth Circuit affirmed, stating that "Abbott has met its burden under *Wyeth*'s clear-evidence standard" and specifically noting the 2005 and 2007 rejections by the FDA of Abbott's proposed changes. *Rheinfrank*, 680 F. App'x at 386.

The record in *Rheinfrank* on this issue is identical to the record currently before the Court. Therefore, the Court concludes that any state law tort claim that is premised upon Abbott's failure to warn of the risk of developmental delay is preempted, as there is clear evidence that the FDA would not have approved such a warning. *See also In re Depakote*, 87 F. Supp. 3d 916, 922 (S.D. Ill. 2015) ("The Court finds that there is clear evidence that the FDA would not have approved a change to the 1999 label to include a warning of developmental delay"); *Hutchens v Abbott Labs., Inc.*, 2016 WL 5661582, at *8 (N.D. Ohio Sep. 30, 2016) ("Therefore, the Court finds Plaintiffs' claim that Defendants' failure to warn of the risks of cognitive developmental delay from use of Depakote by women of childbearing age renders its label inadequate is preempted by federal law").

The plaintiffs present numerous arguments in opposition to summary judgment; some of these were considered and rejected by the Sixth Circuit in *Rheinfrank*, while others are new. The Court will address each in turn.

First, in its own motion for partial summary judgment on the issue of preemption, the plaintiffs argue that "Abbott's First Amendment right to speak gave Abbott the means of complying with Kentucky law and warning about Depakote's risks of developmental delay, autism, and/or autism spectrum disorder." (Pl.'s Mot. for Summ. J. [DN 80-1] at 7.) They argue that, because Abbott has a First Amendment right to speak in a truthful and non-misleading manner about Depakote, it cannot claim that the FDA's rejection of its label changes made it "impossible" for it to comply with the requirements of Kentucky law.

The plaintiffs cite to no standard the Court should look to in evaluating whether Abbott has a First Amendment right to include a warning about developmental delay in the Depakote label or whether the FDA's rules and practices regarding drug labeling unconstitutionally

infringe upon that right. *Compare with Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 553 (2001) (providing standard for First Amendment challenges to commercial speech, including whether speech "concern[s] lawful activity" and is "not . . . misleading," whether "governmental interest is substantial," whether regulation "directly advances" that interest, and whether it is "more extensive" than necessary") (citations omitted). Instead, they cite to a line of cases which pertain exclusively to the marketing, as opposed to labeling, of drugs and seek to apply them to the present case. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011) (finding law that "restricts the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors" unconstitutionally infringes on protected "speech in aid of pharmaceutical marketing"); *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012) (holding that "the government cannot prosecute pharmaceutical manufacturers . . . for speech promoting the lawful, off-label use of an FDA-approved drug"); *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 226 (S.D.N.Y 2015) (enjoining action for misbranding against drug manufacturer, as "truthful and non-misleading speech promoting the off-label use of an FDA-approved drug . . . cannot be the act upon which an action for misbranding is based").

The Court finds each of these cases, as well as the other out-of-circuit district court cases cited, to be distinguishable and unpersuasive. The plaintiffs essentially ask the Court to find that the FDA's authority to reject proposed label changes regarding drug safety amounts to an unconstitutional suppression of a drug manufacturer's speech. None of the cases cited by the plaintiffs support such a broad proposition, and understandably so, given the recognition courts have long given to the role of the FDA in regulating the labeling of drugs. *See Mensing*, 564 U.S. at 612 ("Federal law imposes far more complex drug labeling requirements"). Nor can the plaintiffs argue that Abbott has a First Amendment right to speak outside of the label, as the

FDA still considers such speech to be a part of the drug's "label." *Id.* at 615 (deferring to FDA's opinion that "Dear Doctor letters qualify as 'labeling.' Thus, any such letters must be consistent with and not contrary to [the drug's] approved . . . labeling. A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling") (citations and quotations omitted); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 581 n. 1 (6th Cir. 2011) ("The FDA construes labeling broadly, to include not just the written label associated with the drug, but communications with physicians and other healthcare professionals containing additional warnings ('Dear Doctor' letters) and information published in the *Physician's Desk Reference*") (citing *Mensing*, 564 U.S. at 615). Thus, the cases cited by the plaintiffs are not persuasive.

Comparatively, the Supreme Court in *Wyeth* and *Mensing* spoke directly on the FDA's power to regulate what speech appears in a drug's "label" and when that power takes preemptive effect over what is required by state tort law. The plaintiffs' argument would require the Court to cast aside both cases and the scheme of preemption that they endorse. The Court is not persuaded that the First Amendment requires it to do so. Therefore, the Court rejects the plaintiffs' First Amendment argument.

Second, the plaintiffs argue that preemption is a question of fact that must be submitted to a jury, and that a jury must find that federal law would have prohibited Abbott from complying with state law by "clear and convincing evidence," as opposed to merely "clear evidence." First, as to the standard to be applied, the plaintiffs cite to a Third Circuit case, *In re Fosamax*, 852 F.3d 268, 285–86 (3d Cir. 2017), for the proposition that the "clear evidence" standard stated by the Supreme Court in *Wyeth* is commensurate with the more traditional "clear and convincing" evidentiary standard. The Court need not resolve whether "clear" means "clear and convincing,"

as the Sixth Circuit has already determined that the evidence in *Rheinfrank*, which is identical to the evidence in this case, met the "clear evidence" standard. Therefore, whatever "clear" means, it has been met. As to whether preemption is a question of fact, the plaintiffs cite to *Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 912–13 (6th Cir. 2007), which notes the following standard for evaluating a motion for summary judgment on preemption grounds:

> [T]he basic principles for successfully asserting federal preemption as an affirmative defense on summary judgment are sufficiently clear: it is first incumbent on the party moving for summary judgment to demonstrate that federal preemption potentially applies to the facts and circumstances of the suit, and, if so, the movants must adduce sufficient evidence, interpreted in a light most favorable to the non-moving party, to prove that there is no genuine issue of material fact contradicting the claim that the case at bar actually and unquestionably qualifies for federal preemption. The first step presents a purely legal determination, but the second raises a mixed question. Should the movants fail to meet their burden with respect to the latter step, such as if a genuine issue of material fact exists regarding the claim's actual qualification for federal preemption, the matter must be determined by the factfinder.

Id. at 913 (citations omitted). Abbott argues that this is a pre-*Wyeth* case, and that the post-*Wyeth* body of case law that has developed, including *Rheinfrank*, establishes that preemption is purely a question of law. But again, regardless of whether the Sixth Circuit in *Rheinfrank* was viewing the issue as purely legal or a mixed question of law and fact, it found the record to be sufficient to grant Abbott's motion for summary judgment on preemption grounds. Here, Abbott has met its burden under *Wyeth* to show by clear evidence that the FDA would not have approved any changes to the label that added a warning regarding the risk of developmental delay, and it has also met its burden under *Brown* by first showing that preemption potentially applies to the facts of the case and then adducing sufficient evidence to show that preemption

"actually and unquestionably" applies.[4] Whichever standard the Sixth Circuit actually applied is of no import, since both lead to the same outcome: preemption. Therefore, the plaintiffs' argument on this point is without merit.

Third, the plaintiffs argue that even if preemption applies, it only applies to their claims that the warnings regarding "developmental delay" were inadequate, and that "developmental delay" does not include autism or autism spectrum disorder. They argue that Abbott has not presented clear evidence that the FDA would not have approved a label change that included a warning about autism, and their claims based upon Abbott's failure to warn of this risk are not preempted. Abbott argues in response that the FDA clearly included autism within the umbrella of "developmental delay" when it rejected Abbott's proposed label changes.

The plaintiff in *Rheinfrank* did not suffer specifically from autism. *See Rheinfrank*, 119 F. Supp. 3d at 756 (the plaintiff "has been diagnosed with congenital malformations, facial dysmorphisms, cognitive impairment, developmental delay, and Fetal Valproate Syndrome"). Thus, the Sixth Circuit did not face the issue of whether autism is included within the umbrella term of "developmental delay" for preemption purposes. However, based upon the record presently before the Court, there is clear evidence that the FDA would not have approved a label change to include a warning for autism before the plaintiffs were injured. Abbott has produced its meeting minutes from a teleconference with representatives from the FDA's Division of Neurology Products, including Dr. Katz, from September 2009, the same minutes relied upon by the district court in *Rheinfrank*. (2009 FDA Contact Report [DN 95-16] at 3–5.) The minutes raise questions as to whether the FDA included autism under the umbrella of "developmental delay." (*See id.* at 4) ("Dr. Katz indicated that the data available [for autism] are not sufficiently

[4] The Court is inclined to agree with Abbott that *Wyeth*'s "clear evidence" standard likely abrogates *Brown*'s "actually and unquestionably" language in regards to preemption cases involving FDA labeling requirements. But again, this need not be answered definitively at this time, as both standards have been met.

compelling to be combined with Developmental Delay at this time"). But more importantly, the minutes show that the FDA would not have approved a label change to include a warning of the risk of autism from in utero exposure to Depakote. Under the heading "Autism," the minutes state, "Dr. Katz indicated that the data available is not sufficiently compelling to warrant any language in the label[.]" This language is sufficient to meet the "clear evidence" standard of *Wyeth*, as it demonstrates that the FDA would not have approved a warning in the Depakote label about the risk of autism. This language is very similar to the rejection language regarding developmental delay that both the Sixth Circuit and district court in *Rheinfrank* found sufficient to establish preemption. (*Compare with* 2008 FDA Contact Report [DN 95-13] at 3) ("Dr. Katz stated they can not approve this labeling change at this time.") Nor is this statement merely an example of the FDA having "paid no more than passing attention" to the issue. *Wyeth*, 555 U.S. at 563. Instead, the minutes note that the FDA viewed the data as "worth following up on and is currently under discussion within the Agency. Dr. Katz specifically identified there may be data available from Dr. Holmes (registry); he indicated that in the absence of these data, they may consider an epidemiological study." (2009 FDA Contact Report [DN 95-16] at 5.) Taken together, this is clear evidence that the FDA would not have approved a label change to include a warning of the risk of autism in 2009, as the FDA considered the data available at this time to be insufficient to warrant language on autism in the label. Likewise, this means the same would have been true during Susan Willis' pregnancies. *See Rheinfrank*, 680 F. App'x at 386 ("Given, then, that as of 2008 the FDA did not believe the state of the data supported a developmental delay warning, it stands to reason that as of 2003 [during plaintiff's pregnancy], with even less data to go on, the FDA would similarly have rejected a developmental delay warning"). Thus,

the Court finds that any claims based upon Abbott's failure to warn of the risk of autism are likewise preempted.

Fourth, the plaintiffs argue that evidence of what Abbott knew or should have known prior to the plaintiffs' injuries precludes summary judgment on preemption grounds. They argue that there are factual disputes as to what Abbott knew about the risk of Depakote to the developing fetus, what it should have known, what it could have known had it conducted certain types of testing, and what the FDA could have done with this information. This argument was explicitly rejected by the Sixth Circuit in *Rheinfrank* as speculative and ultimately irrelevant to the issue of preemption:

> Rheinfrank further argues that *Wyeth* makes relevant to a "clear evidence" inquiry not just what Abbott knew but also what it should have known, and that under that standard Abbott fell well short of its responsibility under federal labeling law by refusing to fund or conduct studies probing Depakote's effects on developmental delay. But this argument is too conjectural to defeat preemption. As the Court has explained, speculation as to what a third party or the Federal Government *might* do that would make it lawful for a private party to accomplish under federal law what state law requires of it cannot thwart a claim of preemption, as evidence of that kind would make most conflicts between state and federal law illusory, and thus render conflict pre-emption all but meaningless. That, however, is exactly what Rheinfrank asks this court to accept: a series of speculations as to what the FDA *could* have done with different evidence that Abbott *might* have collected *if* it had run its own studies. Because such speculations are not enough to undermine the clear evidence that the FDA would have rejected a strengthened warning on Depakote's label prior to M.B.D.'s injury, Rheinfrank's failure-to-warn claim is preempted by federal law.

Rheinfrank, 680 F. App'x at 387–88 (citations and quotations omitted). Likewise, in this case, there is clear evidence that the FDA would have rejected a strengthened label prior to the plaintiffs' injuries, and any speculation as to what the FDA may have done had Abbott

performed certain testing remains just that: speculation. Therefore, the Court rejects this argument.

Fifth, the plaintiffs raise evidentiary challenges to some of the documents Abbott uses to show that the FDA would have rejected any proposed label changes. They argue that three of the documents are inadmissible hearsay: the FDA's response to Abbott's proposed label change in 2005 (DN 95-11), the contact report detailing the FDA's rejection of Abbott's proposed label change in 2007 (DN 95-13), and the contact report showing that the FDA would not have approved a label change in 2009.[5] (DN 95-16.) Abbott provides a number of theories under which these documents could be admissible, arguing (1) that the documents contain verbal acts of legal significance that are not considered hearsay, (2) that preemption is a threshold issue for which can be decided purely as a matter of law without applying the rules of evidence, (3) that the alleged hearsay is a command that cannot be hearsay, (4) that the documents fall within the business records exception, (5) that the documents fall within the public records exception, (6) that the Court should apply the residual hearsay exception, and (7) that the plaintiffs have not shown that the evidence contained within the documents could not be presented at trial in an admissible form.

The Court finds the verbal acts doctrine to be applicable to these three documents and the statements contained therein, taking them outside the realm of hearsay. An out-of-court statement is only hearsay if it is offered "to prove the truth of the matter asserted." Fed. R. Evid. 801(c)(2). However, when "legal consequences flow from the fact that words were said," then the statement is not an assertion but rather a verbal act that is not considered hearsay. *Preferred*

[5] The plaintiffs challenge the admissibility of other documents, but only the above three were used by the Court to conclude that clear evidence existed that the FDA would not have approved a label change. Therefore, the Court need not consider the challenge to any other documents, since the plaintiffs only challenge their admissibility in relation to the issue of preemption.

Prop., Inc. v. Indian River Estates, Inc., 276 F.3d 790, 798 n. 5 (6th Cir. 2002). Here, the relevant statements by the FDA, all indicating that it either cannot or will not approve a label change that includes a warning of the risk of cognitive developmental delay or autism, "carr[y] significant legal consequences," as the rejection of the proposed label changes caused the FDA's labeling requirements to preempt state tort law. *Guardian Ins. & Annuity Co., Inc. v. White*, 2014 WL 2515406, at *2 (S.D. Ohio June 3, 2014). While the correspondence and meeting minutes do not fall into the traditional category of documents with independent legal significance, such as a contract, *see Roberson v. U.S. Bank, N.A.*, 831 F.3d 757, 764 (6th Cir. 2016), these out-of-court statements by representatives of the FDA affected Abbott's legal rights and potential liabilities under the law, which is all that is required for the verbal acts doctrine to apply. Thus, the documents have independent legal significance and are not hearsay. *See Zeneca Inc. v. Eli Lilly and Co.*, 1999 WL 509471, at *3 (S.D.N.Y. July 19, 1999) (FDA documents were not hearsay, since "the plaintiff seeks to admit the FDA documents for the fact of what the FDA said to Eli Lilly about Evista . . . Thus, the documents are admissible as non-hearsay").

Finally, the plaintiffs argue that Abbott's evidence is not "indisputable," making it insufficient to meet the "clear evidence" standard under *Wyeth*. Again, this argument is substantially undermined by the Sixth Circuit's conclusion that this exact same evidence did constitute "clear evidence" that the FDA would not have approved a label change regarding the risk of developmental delay. *Rheinfrank*, 680 F. App'x at 386. The plaintiffs raise specific arguments regarding certain documents, which the Court will again limit to only the three documents in which the FDA indicated it would not approve a label change. *See supra* note 5. Generally, the plaintiffs argue that there are questions regarding the credibility of the meeting

minutes and that, because emails and phone calls are not the method by which the FDA formally rejects a proposed label change, they do not indisputably establish that the FDA would not have approved a label change. As to the second of these arguments, the Sixth Circuit explicitly rejected it in *Rheinfrank*:

> [T]he Court in *Wyeth* did not say that for evidence to be clear it must result from a formal procedure of approval or disapproval. Indeed, to require as much would appear to require a rewriting of the Court's chosen test – from whether "the FDA *would not* have approved a change" to a drug's label . . . to whether the FDA *had not* approved it . . . all that Abbott need have done – and did do here – is show that the FDA *would* have rescinded any change in the label, a showing that does not appear the exclude the kind of informal communications from FDA higher-ups that Abbot provided.

Rheinfrank, 680 F. App'x at 386–87 (citations and quotations omitted). The Court holds the same here, as Abbott has provided clear evidence that the FDA *would not* have approved a change. And as to the first argument challenging the credibility of the documents, the questions raised by the plaintiffs are nothing more than "metaphysical doubt[s] as to the material facts" that the Supreme Court has rejected as insufficient to defeat a motion for summary judgment. *Matsushita*, 475 U.S. at 586. The only evidence related to whether the FDA would have approved a label change for Depakote is Abbott's records of the FDA refusing to permit such a change both before and after the plaintiffs' injuries. The plaintiffs' questions about who recorded this information and how it should be read in conjunction with the FDA's later approval of such warnings does not make the evidence any less clear.

Therefore, the plaintiffs' motion for partial summary judgment as to Abbott's preemption defense is **DENIED**. Abbott's motion for summary judgment is **GRANTED** to the extent that any claims that seek to hold Abbott liable for its failure to warn of the risk of developmental delay or autism from in utero exposure to Depakote are preempted.

B. DESIGN DEFECT

Abbott argues that summary judgment is appropriate for the plaintiffs' design defect claim. It makes three arguments on this point: (1) comment k to § 402A to the Restatement (Second) of Torts precludes a design defect claim; (2) the plaintiffs have no expert proof of a feasible alternative design, and (3) design defect claims for prescription drugs after they receive FDA approval are preempted under *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298–99 (6th Cir. 2015). The plaintiffs respond by arguing that Abbott's failure to contraindicate Depakote for women of childbearing potential made its design defective and that contraindication would have been a feasible alternative design for the drug. In its reply, Abbott takes issue with what it views as an attempt to rename what is essentially a failure to warn claim as a defective design claim, since a drug's indications have nothing to do with the composition of the drug but rather its label and warnings.

The Court agrees with Abbott that the plaintiffs cannot pursue a design defect claim based upon the drug's indications. The plaintiffs cite to no cases that support this attenuated definition of "design."[6] Further, a drug's indications and contraindications must be included in its label. *See* 21 C.F.R. § 201.57(a)(6) and (9). Design defect claims focus on the "qualitative or quantitative formulation of the drug products," not information that if included would allow the drug to be used in a safer manner. *Yates*, 808 F.3d at 298. The plaintiffs point to Kentucky cases that seem to endorse a less rigid framework for proving a products liability claim. *E.g.*,

[6] The plaintiffs cite to *C & S Fuel, Inc. v. Clark Equip. Co.*, 552 F. Supp. 340, 247 (E.D. Ky. 1982), and its statement that "a drug might be dangerous to a small percentage of the population with unusually high blood pressure. In such a situation, it might be unreasonably dangerous to market the product without a warning, and the design of the product would be defective if it were marketed in that manner." However, this single statement appears in a discussion of whether a manufacturer of a tractor had a duty to warn of the risk of fire, an issue that the court ultimately found irrelevant, and cites to a law review article that, upon the Court's inspection, does not appear to stand for the proposition that a product's lack of warnings render its design defective. Phillips, Jerry J., *The Standard for Determining Defectiveness in Products Liability*, 46 U. CIN. L. REV. 101, 106 (1977) ("the plaintiff may be able to avoid the complexities of proving design deficiency by alleging warning inadequacy instead"). Thus, the Court does not find the comment in *C & S* equating design and failure to warn defects to be persuasive.

Montgomery Elevator Co. v. McCullough, 676 S.W.2d 776, 780–81 (Ky. 1984) ("Considerations such as feasibility of making a safer product, patency of the danger, warnings and instructions, subsequent maintenance and repair, misuse, and the product's inherently unsafe characteristics, while they have a bearing on the question as to whether the product was manufactured 'in a defective condition unreasonably dangerous,' are all factors bearing on the principal question rather than separate legal questions"). But even if the Court were to examine the plaintiffs' claim under this more holistic approach, the lack of contraindications for the drug would still not be considered a part of its design but rather its "warnings and instructions." Thus, the Court will not let the plaintiffs' claim proceed under a theory that the failure to contraindicate Depakote made the drug's design defective, making Abbott's arguments regarding comment k, feasible alternative designs, and *Yates* preemption moot. Therefore, Abbott's motion for summary judgment as to Count I for strict products liability – design defect is **GRANTED**.

C. CAUSATION

Abbott argues that all claims that seek to hold it liable for the plaintiffs' developmental delay, behavioral conditions, and clinodactyly must be dismissed, as there is no admissible evidence showing that these conditions were caused by the plaintiffs' exposure to Depakote. This argument is premised upon the Court concluding that the plaintiffs' proposed expert opinions as to causation are inadmissible. Therefore, the Court will first consider the relevant motions to exclude or limit the testimony of Drs. Cecil, Lerer, and Privitera.

1. STANDARD OF REVIEW

Fed. R. Evid. 702 permits opinion testimony by witnesses who are sufficiently qualified to testify as experts. The Sixth Circuit has interpreted Rule 702 so as to impose three requirements for expert testimony:

> First, the witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Second, the testimony must be relevant, meaning that it "will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id*. Third, the testimony must be reliable. *Id*.

In re Scrap Metal Antitrust Litig., 527 F.3d 517, 528–29 (6th Cir. 2008). Under Rule 702, the trial judge acts as a gatekeeper to ensure that expert evidence is both reliable and relevant. *Mike's Train House, Inc. v. Lionel L.L.C.*, 472 F.3d 398, 407 (6th Cir. 2006) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999)).

In determining whether testimony is reliable, the Court's focus "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993). The Supreme Court identified a non-exhaustive list of factors that may help the Court in assessing the reliability of a proposed expert's opinion, including: (1) whether a theory or technique can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether the technique has a known or potential error rate; and (4) whether the theory or technique enjoys "general acceptance" within a "relevant scientific community." *Id.* at 592–94. Whether the Court applies these factors to assess the reliability of an expert's testimony "depend[s] on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho*, 526 U.S. at 150 (quotation omitted). "Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity." *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F. 3d 521, 527 (6th Cir. 2012).

While Rule 702 "does not require anything approaching absolute certainty," it requires more than speculation. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671–72 (6th Cir. 2010). Specifically as to an opinion on causation, the Sixth Circuit has stated the following:

> The expert's conclusions regarding causation must have a basis in established fact and cannot be premised on mere suppositions. An expert's opinions, where based on assumed facts, must find some support for those assumptions in the record. However, mere weaknesses in the factual basis of an expert witness' opinion . . . bear on the weight of the evidence rather than on its admissibility.

McLean v. 988011 Ontario, Ltd., 224 F.3d 797, 800–01 (6th Cir. 2000) (internal quotations and citations omitted). *See also In re Scrap Metal Antitrust Litig.*, 527 F.3d at 530 (any weakness in the underlying factual basis bears on the weight, as opposed to admissibility, of the evidence).

Finally, while the parties have requested oral arguments on these motions, the Court finds that it is sufficiently informed, through the briefing of all the motions to exclude and the extensive record developed that includes depositions and expert reports, to rule upon the motions without conducting a hearing or oral arguments. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 248–49 (6th Cir. 2001) (within discretion of district court to hold *Daubert* hearing when issue has been fully briefed by both parties and the record contains "adequate basis" from which to decide the motion) (citations omitted).

2. ANALYSIS

I. DR. ROBERT LERER

The Court begins with the motion to exclude Dr. Lerer's expert testimony on causation, as Abbott argues that other experts improperly relied on Dr. Lerer's inadmissible opinions. Dr. Lerer is a board-certified pediatrician with a subspecialty in developmental pediatrics. (Lerer CV [DN 132-1] at 3.) He performed an in-person pediatric assessment of the plaintiffs. (Lerer Report [DN 115-2] at 17.) In his expert report for this case, he opines "to a reasonable degree of medical certainty" and "in the absence of other possible causes" that the injuries to K.R.W. (diminished intellectual function, and a severe learning disability) and K.W.W. (autism spectrum, attention deficit disorder, and low intelligence) "are the result of in utero exposure to

Depakote."[7] (*Id.* at 20–21.) Abbott does not contest that Dr. Lerer is qualified to offer this opinion, or that the opinion is relevant to the issues in the case; rather, it seeks to exclude this opinion on the basis that Dr. Lerer's methodology is unreliable.

Abbott argues that Dr. Lerer's opinion on causation was not the product of a proper differential diagnosis. Differential diagnosis is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Haryman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001) (quotations omitted). "[A] physician who applies differential diagnosis to determine causation considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history." *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 678 (6th Cir. 2011) (quotations omitted). When differential diagnosis is used to determine causation, the Court must answer three questions to determine if the opinion is sufficiently reliable:

> (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the Court answers "no" to any of these questions, the court must exclude the ultimate conclusion reached.

Tamraz, 620 F.3d at 674. Abbott's motion does not argue that the diagnosis of the plaintiffs' cognitive impairments was inaccurate[8] or that in utero exposure to Depakote was unreliability ruled in as a cause of the plaintiffs' injuries. Instead, it argues that Dr. Lerer's methodology failed to reliably rule out other causes of their injuries. Abbott argues that Dr. Lerer failed to rule

[7] While Dr. Lerer notes that K.R.W. suffers from clinodactyly of the fifth toes and that K.W.W. suffers from physical anomalies and stigmata, he offers no opinion on the cause of these injuries in his report. (Lerer Report [DN 115-2] at 20–21.)

[8] It does argue that the diagnosis of K.R.W.'s clinodactyly was inaccurate, but because Dr. Lerer's report does not make a conclusion as to whether that was caused by in utero exposure to Depakote, the Court need not consider whether Dr. Lerer's opinion that K.R.W. suffers from clinodactyly is admissible at this time.

out potential genetic causes, family history, and environmental and social factors that could better explain the plaintiffs' cognitive impairments. The plaintiffs argue that Dr. Lerer did sufficiently rule out other causes, such as Susan's ingestion of Dilantin during her pregnancy with K.R.W., genetic causes such as Fragile X syndrome and Angelman syndrome, and maternal and paternal history of developmental disorders.

The Court finds that Dr. Lerer's opinion on causation is sufficiently reliable to be admissible under Rule 702. His report and deposition demonstrate that he did consider possible alternative causes that would explain the plaintiffs' cognitive impairments and provided a basis for ruling them out. (*See* Lerer Report [DN 115-2] at 18, 22 (ruling out paternal educational history and K.R.W.'s Dilantin exposure as causes); Dep. Lerer [DN 155-1] at 112:11–19 (ruling out genetic causes).) While Abbott takes issue with how Dr. Lerer ruled out these alternative causes and how much weight and attention he gave to certain evidence and other potential causes, those are "weaknesses in the factual basis of [his] opinion [that] bear on the weight of the evidence rather than on its admissibility." *McLean*, 224 F.3d at 800–01. *See Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 181 (6th Cir. 2009) ("But doctors need not rule out every conceivable cause in order for their differential-diagnosis-based opinions to be admissible"). Abbott may contest Dr. Lerer's conclusions regarding other possible causes of the plaintiffs' injuries through cross-examination. *See Rheinfrank v. Abbott Labs., Inc.*, 2015 WL 13022172, at *7 (S.D. Ohio Oct. 2, 2015) (denying motion to exclude plaintiff's causation expert, as "the fact that other potential causes may remain 'uneliminated' goes to the accuracy of the conclusion, not the soundness of the methodology, and would be properly addressed on cross-examination") (citations omitted). Therefore, Abbott's motion to exclude Dr. Lerer's opinion that the plaintiffs' cognitive impairments were caused by in utero exposure to Depakote is **DENIED**.

II. DR. MICHAEL C. CECIL

Next, Abbott challenges the opinion of Dr. Michael Cecil. Dr. Cecil is a psychologist with a specialization in clinical neuropsychology. (Cecil CV [DN 117-4] at 1.) He performed numerous tests to evaluate the plaintiffs for neuropsychological disorders and diagnosed K.R.W. with an unspecified neurodevelopmental disorder; specific learning disability in the area of reading, writing, and math; and mood disorder secondary to brain dysfunction, while diagnosing K.W.W. with autism spectrum disorder and specific learning disability in mathematics. (Cecil Reports [DN 118-3, 188-4] at 5–6.) However, he also opined in his reports that K.R.W.'s impairments "may be a result of exposure to Depakote in utero" and that K.W.W.'s brain dysfunction "may stem from exposure to Depakote in utero." (*Id.* at 5–6.) Abbott makes three arguments in favor of excluding this opinion on causation. First, it argues that Dr. Cecil is not qualified to offer an opinion on the cause of the plaintiffs' injuries. Second, it argues that Dr. Cecil's methodology in making his causation conclusion is not reliable. And third, it seeks exclusion on the basis that Dr. Cecil changed his opinion that Depakote "may" have caused the injuries in his reports to "more likely than not" in his deposition.

The Court has doubts as to whether Dr. Cecil has the requisite "knowledge, skill, experience, training, or education" to offer an opinion on what caused the plaintiffs' cognitive impairments. Fed. R. Evid. 702. As Abbott points out, almost all of Dr. Cecil's experience and practice has been in diagnosing whether a patient has a neuropsychological disorder, not what could have caused that disorder.[9] (*See* Dep. Cecil [DN 118-1] at 35:13–55:21) (discussing practice.) Further, his knowledge of Depakote and the risks associated with in utero exposure are the product of only twelve articles that he first read while working on his report for the

[9] Abbott raises no objection to Dr. Cecil's opinions as to what injuries the plaintiffs have, only his opinion as to what caused those injuries.

present case. (*Id.* at 198:8–199:15.) The Sixth Circuit "has recognized for some time that expert testimony prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert's line of scientific research or technical work, should be viewed with some caution." *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434 (6th Cir. 2007) (compiling cases). Dr. Cecil's opinion on causation, as opposed to his diagnosis of the plaintiffs' injuries, does not appear to flow naturally from his expertise.

However, even if Dr. Cecil is qualified to offer an opinion on causation, the Court finds his methodology to be unreliable. Beginning with Dr. Cecil's reports, he offers no methodology as to how he concluded that Depakote "may" have caused the plaintiff's injuries. The entirety of Dr. Cecil's report on K.R.W. that pertains to causation reads as follows: "The results of the current evaluation are consistent with neuropsychological impairment that is likely developmental and may be a result of exposure to Depakote in utero in the absence of strong findings consistent with some other neurological process (e.g., traumatic brain injury)." (Cecil Report [DN 118-3] at 5.) Likewise, his discussion of causation in his report on K.W.W. consists of the following: "Overall, it is my opinion that [K.W.W.] has suffered brain dysfunction likely secondary to developmental issues and may stem from exposure to Depakote in utero based upon the extant scientific literature, review of records, as well as his overall neuropsychological profile." (Cecil Report [DN 118-4] at 6.) While his report on K.W.W. provides some detail on what materials were used in forming his opinion, there is no detail at all as to how those materials were used and why they led him to conclude that Depakote may have caused the plaintiffs' injuries. The reports simply mention at the beginning that the children were exposed to Depakote in utero, and at the end it concludes that their injuries may have been caused by that.

Without providing a methodology as to how he reached this conclusion, the report does not "reliably rule in" Depakote as a potential cause. *Tamraz,* 620 F.2d at 674.

Further, Dr. Cecil's deposition does not adequately address the methodological shortcomings of his report, as it does not "reliably rule out" other possible causes. For example, he did not consider family history of academic achievement as a potential alternate cause because "there's so many different variables that go into that, it's hard to sort of make a general statement about that[.]" (Dep. Cecil [DN 118-1] at 104:11–13.) But Dr. Cecil's reason for not considering this factor was *not* because it does not explain the plaintiffs' injuries, but rather because it is difficult to apply. This is not reliably excluding an alternative cause; it is failing to consider it at all. Dr. Cecil was asked directly what his methodology was in determining causation, and he replied, "I don't know of any other neurological issues that those children have been diagnosed with." (*Id.* at 208:15–17.) He later added, "I'm just not aware of anything else that would explain the likelihood of those deficits." (*Id.* at 211:18–19.) But these are vacuous statements that do not offer any substantive evidence of what he *did* consider and reliably rule out as possible alternative causes. Dr. Cecil's conclusion that Depakote may have caused the plaintiffs' injuries "is a plausible hypothesis. It may even be right. But it is no more than a hypothesis, and thus it not 'knowledge,' nor is it based on sufficient facts or data or the product of reliable principles and methods . . ." *Tamraz*, 620 F.3d at 670 (quotations omitted). Dr. Cecil seemed to confirm as much in his deposition:

> I didn't say it was the cause. You're asking me, if you're asking me, what do I most likely think that produced these neuropsychological deficits that these children particularly have, I would say that at the end of the day, that would be the most likely thing that caused their difficulties.

(Dep. Cecil [DN 118-1] at 210:21 – 211:3.) If Dr. Cecil could not then say that Depakote caused the plaintiffs' injuries, then neither can he say it now. Therefore, Abbott's motion to exclude the opinion of Dr. Cecil that Depakote either "may" have caused the plaintiffs' injuries or "more likely than not" was the cause is **GRANTED**.

III. DR. MICHAEL PRIVITERA

Finally, Abbott moves to exclude the opinion of Dr. Michael Privitera that the plaintiffs' "injuries and disabilities are as a result of exposure to valproate in the pregnancies, rather than from any cause, including any exposure to other AEDs during the pregnancy." (Privitera Report [DN 112-2] at 25.) Abbott argues that Dr. Privitera's methodology is unreliable, as he fails to effectively rule out other potential causes of the plaintiffs' injuries.

Part of Abbott's argument rests upon the reliance Dr. Privitera placed on the findings and report of Dr. Lerer. Because Dr. Lerer's opinion and report are based upon an unreliable methodology, according to Abbott, Dr. Privitera's reliance on that opinion and report is likewise unreliable. However, the Court has already determined that Dr. Lerer's opinion is admissible. *See supra* sec. III.C.2.i. Therefore, Dr. Privitera's opinion is not inadmissible for having utilized Dr. Lerer's report. *See Tamraz*, 620 F.3d at 675 ("an expert may in some circumstances rely on other experts' testimony – see Fed. R. Evid. 703").

However, Dr. Privitera's methodology must still otherwise be reliable. In his report, he states that "to a reasonable degree of medical certainty that the physical, cognitive and behavioral abnormalities suffered by [the plaintiffs] are characteristic of and caused by Depakote exposure." (Privitera Report [DN 112-2] at 26.) He explains that this conclusion is based upon the plaintiffs suffering from "physical, cognitive and behavioral features commonly reported among children exposed to Depakote in utero." (*Id.* at 25.) He rules out K.R.W.'s exposure to

Dilantin (referred to as "phenytoin" in the report) as a possible cause of his injuries since that drug "is not associated with a reduction in the full scale IQ of children exposed in utero." (*Id.*) He also explains that

> [t]his case presents a notable example of the dose response and length of exposure effects from in utero Depakote exposure[, as K.R.W.], who was only exposure during the first 8.5 – 9 weeks of pregnancy to 1000 mg a day, suffers from mild-moderate injuries, while [K.W.W.], who was exposed to 2000 mg a day throughout the entire pregnancy, suffers from severe injuries, including autism spectrum disorder.

(*Id.* at 26.) He further clarified in his deposition that he excluded parental IQ and educational achievement on the father's side as a potential cause since his understanding of peer-reviewed literature establishes that "you get more of your cognitive and intelligence function from your mother than your father," so that in "a statistical assessment, the mother's IQ, when you do a multivariate analysis . . . the father's IQ falls out[.]" (Dep. Privitera [DN 112-1] at 108:2–20.)

The Court finds Dr. Privitera's methodology to be sufficiently reliable under Fed. R. Evid. 702. Dr. Privitera's report adequately outlines his methodology and considerations in forming his opinion. While his conclusions may not be the product of a true differential diagnosis, an opinion on medical causation does not necessarily have to be produced through a differential diagnosis. *Daugherty v. Chubb Grp. Of Ins. Cos.*, 2011 WL 552738, at *7 (W.D. Ky. Nov. 14, 2011) (citing *Best*, 563 F.3d at 176). What matters is that the methodology is reliable, and the plaintiffs have adequately demonstrated that Dr. Privitera's methodology in this case was. He clearly outlines what factors he considered (the patients' symptoms, length and dosage of exposure, medical literature) in concluding that Depakote was the cause while also clearly explaining why the other potential causes he considered (Dilantin exposure, paternal IQ) were rejected. This is a sufficient factual basis upon which his conclusions can rest, and any

shortcomings can be addressed on cross examination. *See Rheinfrank*, 2015 WL 13022172, at *7. Therefore, Abbott's motion to exclude the opinion of Dr. Privitera that Depakote caused the plaintiffs' injuries is **DENIED**.

3. EVIDENCE OF CAUSATION

Because Drs. Lerer and Privitera may present their opinions that Depakote caused the plaintiffs' cognitive injuries, the Court rejects Abbott's argument that there is no admissible evidence of causation. However, as noted in the discussion of Dr. Lerer, he has not opined that the plaintiffs' clinodactyly was caused by in utero Depakote exposure. *See supra* note 8. While Dr. Privitera does offer an opinion on Depakote causing the plaintiffs' clinodactyly, the plaintiffs assert that they "are not seeking to prove that the clinodactyly of toes was caused [by] in utero exposure to Depakote." (Pl.'s Resp. to Mot. to Exclude Privitera [DN 148] at 26.) Given this concession, the Court accepts Abbott's argument as to there being no admissible evidence of causation in regards to the plaintiffs' clinodactyly, and the motion for summary judgment is **GRANTED** as to any claim that seeks to recover for the plaintiffs' clinodactyly.

D. NEGLIGENT MISREPRESENTATION AND FRAUD

Finally, Abbott argues that summary judgment is appropriate on Count IV under both of plaintiffs' theories of recovery: negligent misrepresentation and fraud. It argues that the plaintiffs' have not identified any affirmative false statements that would support a negligent misrepresentation claim. It further argues that there is no evidence upon which the jury could find that such statements were made knowingly or recklessly or that they were relied upon by Susan Willis' prescribing doctors, as is required for a fraud claim. The plaintiffs respond by identifying several statements in the Depakote label they allege are false, pointing to the

depositions of Susan's prescribing doctors to demonstrate reliance, and arguing that Abbott either knew or should have known these statements were false.

First, as to the claim of negligent misrepresentation, Kentucky follows the Restatement (Second) of Torts § 552. *Presnell Const. Mgrs., Inc. v. EH Const., LLC*, 134 S.W.3d 575, 580–81 (Ky. 2004). Section 552 reads in pertinent part:

> One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Further, "negligent misrepresentation requires an affirmative false statement," not merely an omission. *Giddings & Lewis, Inc. v. Indus. Risk Ins.*, 348 S.W.3d 729, 746 (Ky. 2011). Plaintiffs allege that the Depakote label contains the following false statements:

- "Although data are more extensive with respect to trimethadione, paramethadione, phenytoin, and phenobarbital, reports indicate a possible similar association [between use and birth defects] with the use of other antiepileptic drugs"
- "Sufficient data to determine the incidence of these congenital anomalies is not available"
- "The higher incidence of congenital anomalies in [AED]-treated women with seizure disorders cannot be regarded as a cause and effect relationship"
- "There are intrinsic methodological problems in obtaining adequate data on drug teratogenicity in humans"

(Pl.'s Resp. to Mot. for Summ. J. [DN 141] at 12.) Abbott's objections to these statements as being affirmatively false is general, as it simply notes that there is insufficient evidence to prove that these statements were false. The Court rejects this argument, as the plaintiffs' have submitted expert testimony that, if believed by the jury, would allow jurors to conclude that the statements were false. (*See* Privitera Report [DN 112-2] at 7) (arguing data was available in

1999 showing Depakote caused more malformations than other AEDs.) Likewise, these experts can argue that Abbott either knew or should have known they were false when conveying them. (*See id.*)

Further, there is sufficient evidence of reliance on these statements by Dr. Chou, Susan's doctor during her pregnancy with K.W.W. He testified that, in 2005, he was under the assumption that all AED's had similar risks regarding potential birth defects. (Dep. Chou [DN 65-1] at 67:3–68:14.) This statement supports the claim, as it is evidence that Dr. Chou relied on the information in the label. Thus, the plaintiffs may argue that Dr. Chou relied on the alleged falsities in the Depakote label, and Abbott's motion for summary judgment as to the claim for negligent misrepresentation is **DENIED**. However, the alleged misrepresentations all pertain to the risk of birth defects. There is no admissible evidence that Depakote exposure caused clinodactyly, K.R.W.'s only alleged birth defect. *See supra* sec. III.C.3; Pl.'s Resp. to Mot. for Summ. J. [DN 141] at 7–8 (listing injuries as clinodactyly and various cognitive disabilities). Therefore, K.R.W. cannot assert a claim for negligent misrepresentation, as he suffered no cognizable injury that was allegedly caused by the misrepresentations, and the motion for summary judgment is **GRANTED** as to K.R.W.'s claim.

As for the fraud claim, Kentucky law requires the plaintiff to establish six elements by clear and convincing evidence: "(1) a material misrepresentation, (2) which is false, (3) known to be false or made recklessly, (4) made with inducement to be acted upon, (5) acted in reliance thereon, and (6) causing injury." *Derby City Capital, LLC v. Trinity HR Servs.*, 949 F. Supp. 2d 712, 726 (W.D. Ky. 2013) (citations omitted). In addition to the statements supporting the negligent misrepresentation claim, the plaintiffs also reference numerous omissions of material fact that support their claim of fraud, including Abbott's failure to disclose the elevated risk of

using Depakote as compared to other AEDs, as well as the risk of autism and decreased IQ scores.

First, the plaintiffs' fraud by omission claims pertaining to the risk of developmental delay and autism are preempted for the same reasons that the strict products liability and negligence claims based upon the failure to warn of the risk of developmental delay and autism are preempted. Abbott cannot be held liable under state tort law for not saying something about the risk of developmental delay and autism that federal law prevented it from saying. However, the Court will allow the fraud by misrepresentation claims to proceed for reasons similar to the negligent misrepresentation claims. The same expert testimony that supports the negligent misrepresentation claim supports the fraud by misrepresentation claims, as it can be used to prove that these statements were material, actually false, and that Abbott knew or should have known this. (*See* Privitera Report [DN 112-2] at 7). Likewise, the same evidence as used to support the reliance element in the negligent misrepresentation claim supports the reliance element here. And the plaintiffs cite to internal Abbott documents that tend to show that these statements were made with the intent to induce additional sales of Depakote. (DN 141-11, 141-12.). Therefore, the plaintiffs' fraud claim may proceed as limited by the Court's findings regarding preemption, and the motion for summary judgment as to the fraud by misrepresentation claims is **DENIED**.

Again, though, the Court notes that the alleged fraudulent statements all pertain to birth defects, meaning that K.R.W.'s claim for fraud must be dismissed due to a lack of any evidence that Depakote caused his only alleged birth defect, clinodactyly. This will result in a total dismissal for K.R.W.'s claims: the claims based on his developmental delay are preempted, and

the claims based on his clinodactyly fail from their lack of causation evidence. Therefore, K.R.W. is **DISMISSED** as a plaintiff.

IV. CONCLUSION

Therefore, for the foregoing reasons, the Court orders the following:

(1) The plaintiffs' motion for partial summary judgment (DN 80) is **DENIED**;

(2) The defendants' motion for summary judgment (DN 95) is **GRANTED IN** and **PART DENIED IN PART** to the following extent:

(a) The motion for summary judgment as to Count I for strict products liability (design defect) is **GRANTED**;

(b) The motion for summary judgment as to Count II for strict products liability (failure to warn) is **GRANTED** as to any theory of recovery based upon the defendants' failure to warn of the risk of developmental delay and autism;

(c) The motion for summary judgment as to Count III for negligence is **GRANTED** as to any claim based upon the defendants' failure to warn of the risk of developmental delay and autism;

(d) The motion for summary judgment as to Count IV for negligent misrepresentation and fraud is **GRANTED** as to K.R.W.'s claims and **DENIED** as to K.W.W.'s claims;

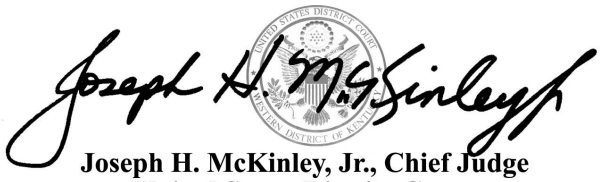
(e) The motion for summary judgment as to Counts V–VII for various breach of warranty claims is **GRANTED**; and

(f) Plaintiff K.R.W. is **DISMISSED** as a plaintiff from this action;

(3) The defendants' motion to exclude the expert testimony of Dr. Robert Lerer on causation (DN 89) is **DENIED**;

(4) The defendants' motion to exclude the expert testimony of Dr. Michael Cecil on causation (DN 87) is **GRANTED**; and

(5) The defendants' motion to exclude the expert testimony of Dr. Michael Privitera on causation (DN 92) is **DENIED**.



Joseph H. McKinley, Jr., Chief Judge
United States District Court

December 1, 2017

cc: counsel of record